ANDA 75-404 November 28, 2001

Danbury Pharmacal Inc.
Attention: Helen Anne Ostrosky
P.O. Box 450
39 Mt. Ebo Road
Brewster, NY 10509

Dear Madam:

This is in reference to your abbreviated new drug application dated June 25, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Famotidine Tablets USP, 10 mg(OTC).

Reference is also made to your amendment dated September 28, 2001.

The listed drug product (RLD) referenced in your application, Pepcid AC Tablets of Merck Research Laboratories, is subject to periods of patent protection which expire on November 2, 2015 (U.S. Patent No. 5,667,794 the '794 patent), and June 29, 2016 (U.S. Patent No. 5,854,267 the '267 patent). Your application contains a Paragraph IV Certification to both the '794 and '267 patents under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on either of the patents, or the patents are invalid or unenforceable. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of either patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(I) is received by the patent holder and the holder of the new drug application (NDA) for the RLD. You have notified the Agency that Danbury Pharmacal, Inc. (Danbury) has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for infringement against either the '794 and '267 patents was brought against Danbury within the statutory forty-five day period.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted Over-The-Counter (OTC) labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Famotidine Tablets, 10 mg to be bioequivalent to the listed drug (Pepcid AC® Tablets, 10 mg of Merck Research Laboratories). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

With respect to 180-day generic drug exclusivity, we note that Danbury was the first ANDA applicant to submit a substantially complete ANDA containing a Paragraph IV Certification to the '267 patent. Therefore, with this approval, Danbury is eligible for 180-days of generic drug exclusivity. Such exclusivity will begin to run either from the date Danbury begins commercial marketing of the drug product, or in the absence of marketing, from the date of a decision of a court finding the patent to be invalid or not infringed, whichever event occurs earlier [Section 505(j)(5)(B)(iv)].

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98.

The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research